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10/824,688	04/14/2004	Christopher J. Scwall	60382USA	8069

7590

03/06/2006

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EXAMINER

WHITE, EVERETT NMN

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/824,688

Applicant(s)

SEWALL ET AL.

Examiner

Everett White

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/26/04 & 9/23/04, 11/8/04, 8/15/05, 11/14/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 43, last line, the term "solution" lacks clear antecedent basis which renders the claim indefinite.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 44 and 45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-17, 20, 21 and 23-27 of copending Application No. 10/824,793 in view of Guiseley (US Patent No. 4,443,486). Both applications disclose a delivery system comprising a homogenous,

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thermoreversible gel film, wherein said gel film comprises: (i) a film forming amount of a carrageenan and optionally at least one of a plasticizer, a second film former, a bulking agent, and a PH controlling agent; and (ii) an active substance; wherein the active substance is at least one member selected from the group consisting of an oral care agent, a breath freshening agent, an antimicrobial agent, a cooling agent, a pharmaceutical agent, a nutraceutical agent, a salivary stimulant agent, a vitamin, a mineral, a coloring agent, cosmetic ingredient, agricultural active, a sweetener, a flavorant, a fragrance and a food.

The instantly claimed delivery system differs from the delivery system of the 10/824,793 application by claiming the use of a low molecular weight carrageenan having a viscosity of 5 to less than 10 cP at 75°C.

However, the Guiseley patent discloses preparation of a modified extractive comprising carrageenan and teaches that hydrolysis can be used to decrease the viscosity of a 1.5% water solution of hydrocolloid extractive at 75°C to within the range of from about 5-20 mPa.s (See column 6, lines 37-39), which covers part of the viscosity range disclosed in instant claim 44.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of Applicants invention to further subject the carrageenan used in the preparation of gels and capsules of the delivery system of the 10/824,793 application to hydrolysis in order to reduce the viscosity of carrageenan thereof in view of the recognition in the art, as evidenced by the Guiseley patent, that carrageenan having such viscosity is an effective ingredient for gel-forming products which can be consumed orally in various forms from capsule filled materials to edible dessert gels.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 1, 6, 7 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guiseley (US Patent No. 4,443,486).

Applicants claim a homogeneous, thermoreversible gel comprising carrageenan wherein said carrageenan has a viscosity of 5 to less than 10 cP at 75°C when measured in a 0.10 molar aqueous sodium chloride solution containing 1.5% by weight of said carrageenan based on the weight of all components in said solution, and optionally at least one of a plasticizer, a second film former, a bulking agent, and a pH controlling agent, wherein said gel has a solids content of at least 40% and said carrageenan is present in an amount of at least 70% of all carrageenan present in said gel.

The Guiseley patent discloses a stabilizer for milk products comprised of a carrageenan extractive of *Eucheuma cottonii* seaweed having a water viscosity at 1.5% concentration and 75°C of not less than 5 mPa.s and not more than about 20 mPa.s

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(see abstract). The Guiseley patent discloses that it is well known in the art that carrageenan from members of the class Rhodophyceae (red seaweeds) has been used for many years to modify the properties and texture of milk and milk products. For example, the Guiseley patent discloses that sun bleached, washed seaweed (Irish moss, i.e., *Chondrus crispus* species), which contains carrageenan has been used for centuries to prepare a pudding known as blanc mange, by heating the seaweed in milk and allowing the milk, with or without sugar and flavorings, to cool, whereupon a gel results.

The Guiseley patent does not set forth the viscosity of the carrageenan containing Irish moss seaweed used to prepare the gel pudding, which is recited for the gel in the instant claims.

It would be obvious to substitute the carrageenan extractive of *Eucheuma cottonii* seaweed having a water viscosity at 1.5% concentration and 75°C of not less than 5 mPa.s and not more than about 20 mPa.s of the Guiseley patent for the carrageenan containing Irish moss seaweed in order to prepare a gel pudding since it is within the skill of one having ordinary skill in this art to improve or change the taste and texture of gel puddings.

7. Claims 2-5, 8-27, 29, 30-34, 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guiseley (US Patent No. 4,443,486) as applied to Claims 1, 6, 7 and 28 above, and further in view of Gennadios (US Patent No. 6,214,376).

Applicants claim a homogeneous, thermoreversible gel comprising carrageenan wherein said carrageenan has a viscosity of 5 to less than 10 cP at 75°C when measured in a 0.10 molar aqueous sodium chloride solution containing 1.5% by weight of said carrageenan based on the weight of all components in said solution, and optionally at least one of a plasticizer, a second film former, a bulking agent, and a pH controlling agent, wherein said gel has a solids content of at least 40% and said carrageenan is present in an amount of at least 70% of all carrageenan present in said gel. Additional limitations in the dependent claims include the gel wherein carrageenan is at least one of iota Carrageenan, kappa Carrageenan or kappa-2 carrageenan; the

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gel the carrageenan is at least 80% by weight iota carrageenan, or kappa carrageenan, or kappa-2 carrageenan based on the total weight of all carrageenan in the gel and the gel has a gelling temperature of 60°C or less; the gel wherein said second film former is selected from the group consisting of starch, starch derivative, starch hydrozylate, cellulose gums, alginates, propylene glycol alginate, polymannan gums, dextran, pectin, gellan, pullulan, alkylcellulose ethers, modified alkyl cellulose ethers; the gel wherein the plasticizer is at least one member selected from the group consisting of glycerin, sorbitol, polydextrose, maltitol, lactitol, and polyalkylene glycols; the gel wherein the bulking agent is at least one member selected from the group consisting of microcrystalline cellulose, microcrystalline starch, starch, starch derivatives, inulin, starch hydrozylates and polydextrose; Soft capsules comprising said gel; the soft capsules having an encapsulated substance selected from the group consisting of pharmaceuticals, vitamins, nutritional supplements, paint, paintballs, pigments, agriculturals, cosmetics, antioxidants, flavorant and food; claims drawn to a solid form comprising a fill material encapsulated by said gel; the solid form wherein the filled material is a powder, tablet, caplet, microcapsule or capsule; claim drawn to hard capsules comprising a fill material encapsulated by said gel; and claims drawn to a delivery system comprising a homogenous, thermoreversible gel film.

The Guiseley patent discloses a stabilizer for milk products comprised of a carrageenan extractive of *Eucheuma cottonii* seaweed having a water viscosity at 1.5% concentration and 75°C of not less than 5 mPa.s and not more than about 20 mPa.s (see abstract), wherein it is well known in the art, as discussed in the above rejection, of using seaweed containing carrageenan to prepare gel pudding by heating the seaweed in milk and allowing the milk, with or without sugar and flavorings, to cool, whereupon a gel results.

The carrageenan gel composition of the instant claims differs from the carrageenan containing gel composition of the Guiseley patent by further claiming said gel wherein the carrageenan is at least one of iota carrageenan, kappa carrageenan or kappa-2 carrageenan; said gel containing specific amounts of carrageenan; said gel comprising a plasticizer, a second film former, a bulking agent, and a pH controlling

agent; said gel in soft capsules, hard capsules, and of solid forms; and a delivery system comprising a gel and carrageenan.

The Gennadios patent discloses a gelatin-free capsule for use in oral administration of medicines, cosmetic or bath applications, or dietary supplements which can be prepared from compositions comprising (a) 8-50% by weight of water-dispersible or water-soluble plasticizer, (b) 0.5 to 12% by weight .kappa.-carrageenan, (c) 0 to 60% dextrins, and (d) 1% to 95% by weight water, with the .kappa.-carrageenan comprising at least 50% by weight of all gums forming or contributing to formation of thermoreversible gels in the composition (see abstract). The Gennadios patent discloses that a capsule for oral administration or cosmetic application may comprise a fill material to be administered to a patient or subject, wherein the capsule comprises an aqueous based film comprising (a) water-dispersible or water-soluble plasticizer, and (b) carrageenan, with the carrageenan comprising at least 50% or 75% by weight of .kappa.-carrageenan, and the carrageenan comprising at least 50% or 75% by weight of all gums which form or contribute to the formation of thermoreversible gels (see abstract). This description of the gelatin-free capsule of the Genndios patent embraces the subject matter of instant Claims 2, 4, 28-34, 44 and 45. See column 2, lines 3 and 4 wherein the Gennadios patent discloses that kappa-carrageenan is known to form gels in the presence of potassium cations, which embraces the subject matter of instant Claim 9. Also see column 3, lines 37-39, wherein the Genndios patent discloses that gelling salts can be salts of divalent cations such as calcium, magnesium, barium or salts of monovalent cations such as potassium and sodium, which embraces the subject matter of instant Claims 9-14. See column 3, lines 44-54, wherein the Gennadios patent discloses that carbohydrates such as glycerin, alkylene glycols, sorbitol, maltitol, lactitol, xylitol, corn syrup solids, and other polyols or combinations thereof can be used as plasticizers, which is identical to the plasticizers disclosed in instant Claim 26 and embraces the use of plasticizers in instant Claims 1, 8 and 44. See column 4, 2nd paragraph wherein the Gennadios patent discloses that mannan gums (e.g., locust bean gum, konjac gum, and tara gum) which have a synergistic gelling effect with .kappa.-carrageenan can be added to increase gel strength and elasticity. In this

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paragraph, Gennadios also discloses that part of the .kappa.-carrageenan may be substituted by iota-carrageenan (up to a maximum of 50% or 25% by weight of the .kappa.-carrageenan) which forms "softer" and more elastic gels. This description of the combination of .kappa.-carrageenan with other mannan gums and iota-carrageenan embraces the use of a second film former disclosed in instant Claims 1-5, 25, 26 and 44. The Gennadios patent further discloses that hydrolyzed starches, such as maltodextrin are added to (1) increase solids concentration in the gel mass (2) aid heat sealing by increasing wet film tackiness, and (3) prevent "hazing" of dried carrageenan capsules induced by the gelling salt and, if added, the mannan gums, wherein maltodextrin from corn starch is optionally used due to wide availability and low cost. The material added by Gennadios to increase solids concentration in the gel mass meet the requirement of using bulking agents in instant Claims 1, 26 and 44.

One of ordinary skill in this art would be motivated to combine the teachings of the Guiseley patent with the teachings of the Gennadios patent since both patents set forth carrageenan containing gel compositions that are edible with food.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the carrageenan having a viscosity at 1.5% concentration and 75°C of not less than 5 mPa.s and not more than about 10 mPa.s of the Guiseley patent as a gel food stabilizer in view of the recognition in the art, as evidenced by the Gennadios patent, that carrageenan is an effective ingredient for gel-forming products which can be consumed orally in various forms from capsule filled materials to edible dessert gels.

8. Claims 35-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gennadios (US Patent No. 6,214,376) in view of Guiseley (US Patent No. 4,443,486).

Applicants claim a process for preparing the homogeneous gels comprising the steps of: (i) heating, hydrating, mixing, solubilizing and, optionally, de-aerating a composition of carrageenan and optionally at least one of a plasticizer, a second film former, a bulking agent, and a pH controlling agent in an apparatus providing sufficient shear, temperature and residence time to form a homogeneous, thermoreversible,

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molten composition, wherein said temperature is at or above the solubilizing temperature of said composition; (ii) and cooling said molten composition at or below its gelling temperature to form the gel. Additional limitations in the dependent claims include the process wherein the molten composition is fed directly into at least one of a mixer, pump or devolatilizer prior to cooling; the process wherein said apparatus is a Ross mixer, Stephan processor, extruder, jet cooker or fluid mixing apparatus.

The Gennadios patent discloses a process for forming the capsules (the delivery system) comprising heating the composition, casting or extruding the composition into a film, gelling the composition by cooling, associating a fill material with the gelled composition (usually as a film) and sealing the film about the fill material (see abstract). Additional process information is provided in the Example in column 6, which discloses a .kappa.-carrageenan or a blend of .kappa.-carrageenan and iota-carrageenan/gelling salt/mannan gum/xanthan gum (if these materials are present) is dispersed, e.g., at ambient or at least slightly elevated temperature (higher temperatures, of course, usually being advantageous in the physical dissolution of most materials), in a plasticizer (or mixture of plasticizers). Optional additives (e.g., the maltodextrin, gum arabic and protein) are dissolved in water (preferably at about ambient temperature, but some slight elevation or reduction in temperature may be used) to form an aqueous solution. The aqueous solution is added to the .kappa.-carrageenan/plasticizer mixture to form a working composition. The working composition is heated, preferably with stirring to above 130° F to below the boiling point of the working mixture. The heated working composition can then be transferred or introduced for processing to a conventional gelatin encapsulation machine (films are formed by casting the solution on cooled rotating (e.g., metal such as steel) drums, the films are fed through a series of rollers to counter-rotating dies which form, cut and fill capsules of various sizes.

The process for preparing the gel and capsule of the instant claims differs from the preparation of the gel and capsules of the Gennadios patent by claiming a gel comprising carrageenan wherein said carrageenan has a viscosity of 5 to less than 10 cP at 75°C.

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However, the Guiseley patent shows that preparation of carrageenan compositions having low molecular weight is known in the art. The Guiseley patent discloses carrageenan extractive of *Eucheuma cottonii* seaweed having a water viscosity at 1.5% concentration and 75°C of not less than 5 mPa.s and not more than about 20 mPa.s. (see abstract), which covers the viscosity values for the carrageenan disclosed in instant claims. See column 6, lines 37-39, wherein Guiseley discloses preparation of a modified extractive wherein hydrolysis decreases the viscosity of a 1.5% water solution of hydrocolloid extractive at 75°C to within the range of from about 5-20 mPa.s.

One of ordinary skill in this art would be motivated to combine the teachings of the Guiseley patent with the teachings of the Gennadios patent since both patents set forth carrageenan containing gel compositions that are edible with food.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of Applicants invention to further subject the carrageenan used in the preparation of gels and capsules of the Gennadios patent to hydrolysis in order to reduce the viscosity of carrageenan thereof in view of the recognition in the art, as evidenced by the Guiseley patent, that carrageenan having such viscosity is an effective ingredient for gel-forming products which can be consumed orally in various forms from capsule filled materials to edible dessert gels.

Information Disclosure Statement

9. The information disclosure statement filed Jul. 26, 2004, Aug. 15, 2005 and Nov. 14, 2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Summary

10. All the claims are rejected.

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Examiner's Telephone Number, Fax Number, and Other Information

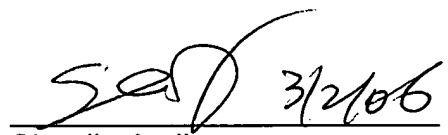
11. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang, can be reached on (571) 272-0627. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.


E. White


Shaojia A. Jiang
Supervisory Primary Examiner
Technology Center 1600

Continuation of Attachment(s) 6). Other: Information Disclosure Statements (PTO-1449) Considered: Nov. 8, 2004, Aug. 15, 2005, Nov. 14, 2005 & Jan. 9, 2006..